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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,694

10/18/2005

Yoshitaka Izumoto

IZUMOTO 1

2025

1444 7590 04/07/2009
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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

04/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/553,694</p>	<p>Applicant(s) IZUMOTO ET AL.</p>	
	<p>Examiner Patricia A. Duffy</p>	<p>Art Unit 1645</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 April 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: _____.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that one would not extrapolate the immunogenicity of the Sholtz et al fusions to the fusion protein of Furutani because one would recognize the structural differences between a PPIase folding factor and the ring structure of the chaperonins and would expect that the structure would affect the ability of the fusion proteins ability to induce an immune response to the target antigen. This assertion is unsupported by evidence and affidavits of record and counsel's unsupported arguments and allegations, which cannot take the place of clear and convincing unobviousness. Ex parte C 27 USPQ2d 1492 (BPAI 1992). Additionally, Applicants own specification teaches that PPIases (folding factors) of the art of Scholz et al are also suitable immunogens and did not discriminate between them. Furthermore, the recitation of fusion protein immunogen in the body of the claim indicates that the immunogen is the fusion protein and the art teaches that fusion proteins are appropriate immunogens. Applicants mischaracterize an immune response as needing an intact antigen. It is well understood by immunologists that the T cell immune response does not require an intact antigen and in fact it requires processing of the antigen by accessory cells called antigen presenting cells and presentation of short parts of the antigen on the antigen presenting cell surface. As such, there is no reason to a priori believe that the intact fusion protein would not be processed appropriately to generate an immune response against the antigen. Applicants argue B cell response and the claims are simply not so limited. Applicants argue a better immune response using a particular species is clearly not commensurate in scope with these claims. A showing of unobviousness must be commensurate in scope with the claims which the evidence is offered to support, to warrant the allowance of generic claims, the showing of unobviousness must include enough examples to be reasonably representative of the genus. Although objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support, the probative value of a narrow range of data can be reasonably extended to prove the unobviousness of a broader claimed range when one could ascertain a trend in the exemplified data which would allow him to reasonably extend the probative values thereof. In re Clemens et al. 206 USPQ 289 (CCPA 1980). In re Kollman et al. 201 USPQ 193 (CCPA 1979). Proving one species of the claimed class of compounds imparts unobvious properties to the claimed composition does not lay the basis for claiming all members of the class. Ex parte Kucera 165 USPQ 332 (POBA 1970). Finally, Applicant has a burden of indicating how the examples representing the claimed invention relate to the prior art examples and how the latter represent the closest prior art, submitting evidence reasonably commensurate in scope with the claimed subject matter, establishing that the differences are in fact unexpected and unobvious and of statistical and practical significance. Ex parte Gelles, 22 USPQ2d 1318 (BPAI 1992). The two limited examples does not allow the skilled artisan to establish the trend commensurate in scope with these claims. The examples were with specific number of chaperonins with the antigen of a HT1Ar at a specific position in the fusion. As such, the alleged improved/unexpected results are not commensurate in scope with the claims. The rejection is therefore maintained.